PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P20027PC01	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. **PCT/AU2004/001490**	International filing date *(day/month/year)* 28 October 2004	Priority date *(day/month/year)* 31 October 2003
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61M 1/12, C08J 7/18		
Applicant VENTRACOR LIMITED et al		

This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. [X] *(sent to the applicant and to the International Bureau)* a total of **12** sheets, as follows:

- [ ] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
4 March 2005	9 November 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **BAYER MITROVIC** Telephone No. (02) 6283 2164

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001490

Box No. I Basis of the report

1. With regard to the **language,** this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1 (b))

   ☐ publication of the international application (under Rule 12.4)

   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

   ☐ the international application as originally filed/furnished

   ☒ the description:

   page **1** as originally filed/furnished
   pages* **2-12** received by this Authority on **4 March 2005** with the letter of **4 March 2005**
   pages* received by this Authority on with the letter of

   ☒ the claims:

   pages as originally filed/furnished
   pages* as amended (together with any statement) under Article 19
   page **13** received by this Authority on **4 March 2005** with the letter of **4 March 2005**
   pages* received by this Authority on with the letter of

   ☒ the drawings:

   pages **1/3-3/3** as originally filed/furnished
   pages* received by this Authority on with the letter of
   pages* received by this Authority on with the letter of

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing (*specify*):
   ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing (*specify*):
   ☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001490

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **1-9**	**YES**
	Claims	**NO**
Inventive step (IS)	Claims **1-9**	**YES**
	Claims	**NO**
Industrial applicability (IA)	Claims **1-9**	**YES**
	Claims	**NO**

2. Citations and explanations (Rule 70.7)

Following documents cited in ISR are considered:

D1: US 5503615. This document discloses ventricular assist device having impeller powered by electric motor. Impeller is made from biocompatible materials such as polyacrylates or rubber, which are also known as good electric insulators. Other materials are also used (titanium alloys or ceramics).

D2: US 5078741, D3: US 4944748. These two documents disclose a rotary blood pump having magnetically operated and magnetically suspended impeller. Blood compatible materials such as plastics are used to coat component parts (see eg. column 7 line 20 – column 9 line 10 of D2).

D4: US 6120537. This document discloses a rotary blood pump having impeller operated by electric motor (column 10 lines 17-36). Surfaces in contact with blood are covered by biocompatible materials such as plastics (column 5 lines 5-13). Hydrodynamic bearings are used to suspend the impellor (column 10 line 50 – column 11 line 20).

D5: EP 1285671 and D6: WO 9901663 disclose different design solutions for electric motor operated rotary blood pumps which use biocompatible coatings on surfaces in contact with blood. Especially D6 discloses the use of hydrodynamic bearings to suspend rotor (page 2 line 24 – page 3 line 10).

D7: Patent Abstracts of Japan JP 07-204263. This document discloses the use of corona or glow discharge treatment of polymer surfaces in contact with blood to make them biocompatible. Examples of surfaces in contact with blood are that of artificial heart pump, etc.

None of the documents D1-D7 disclose a rotary blood pump including a motor adapted to magnetically rotate an impeller and having an insulative member formed from a biocompatible and impermeable polymer and disposed between the portions of the motor to reduce eddy current losses.

NOVELTY AND INVENTIVE STEP – CLAIMS 1-9

In light of the above observations the subject matter of these claims is new and meets the requirements of Article 33(2) PCT with regard to novelty.
The subject matter of these claims is also not obvious and meets the requirements of Article 33(3) PCT with regard to inventive step.

The invention defined in claims 1-11 is industrially applicable.

It is an object of the present invention to address or ameliorate one or more of the abovementioned disadvantages.

Brief Description of the Invention

In accordance with a first aspect the present invention consists in a rotary blood pump including: a motor adapted to magnetically rotate an impeller within a housing; characterised in that the impeller or the housing are formed of a composite material and said composite material includes a first material that is a relatively, insulative, biocompatible and impermeable polymer, and wherein the pump includes an insulative member formed from said first material and is disposed between portions of the motor to reduce eddy currents losses.

Preferably the composite material includes a second material that reinforces the polymer.

Preferably said first material has been surface modified by treatment of plasma immersion ion implantation.

Preferably said impeller includes magnets that are encapsulated by an impermeable fluid barrier.

Preferably said first material is: PEEK, FRP, PC, PS, PEPU, PCU, SiU, PVC, PVDF, PE, PMMA, ABS, PET, PA, AR, PDSM, SP, AEK, T, MPP or a combination thereof.

Preferably said impeller is hydrodynamically suspended.

In accordance with a second aspect the present invention consists in a rotary blood pump including: a motor adapted to magnetically rotate a hydrodynamically suspended impeller within a housing; characterised in that the impeller and/or the housing are formed of a composite material, said pump including at least one insulative member disposed between portions of said motor to reduce eddy current losses and said insulative member is substantially formed from a biocompatible and impermeable polymer.

Preferably said composite material includes a metal metallic alloy.

Preferably said metallic alloy is a titanium alloy.

Brief Description of Drawings

Embodiments of the invention will now be described with reference to the drawings in which:

Fig. 1 shows a cross-sectional view of a first preferred embodiment of the present invention;

Fig. 2 shows an enlarged cross sectional view of a portion of the preferred embodiment shown in Fig. 1; and

Fig. 3 shows an enlarged rotated top view of a portion of the preferred embodiment shown in Fig. 1.

Detailed Description of Embodiments

A first embodiment of the present invention is shown in Fig. 1. In this embodiment, a blood pump 13 made of a composite material, wherein the composite material includes at least a portion of polymer material reinforced with a second material which may preferably be titanium alloy or other wear resistance and biocompatible material. This blood pump 13 may include: an inlet 1 and an outlet 8; an impeller 2 which rotates and propels blood from the inlet 1 using centrifugal propulsion through the pump housing 6 to the outlet 8; a motor generates the torque force for rotating the impeller 2, the motor is formed by the interaction of the stators 5 axially mounted within the pump housing 6 interacting with magnetic regions in the impeller 2.

Preferably, the impeller 2, in use, is hydrodynamically suspended on a fluid bearing formed by a restriction gap 9 between the blades 3 of impeller 2 and the inner wall of the pump housing 6. The impeller 2 preferably includes four blades 3 joined together by struts 4 in a generally square configuration.

Preferably positioned between the stators 5 and the magnetic regions of the impeller 2 is an insulative member 7. This insulative member 7 is electrically non-conductive and may be constructed of polymers. The insulative member 7 functions so as to prevent or minimise the build up of electrical eddy currents between the stators 5 and magnetic regions of the impeller 2. The eddy currents interfere with the transfer of EMF onto the impeller 2 and may lead to a reduction of electrical efficiency. Once the eddy currents are reduced or minimised, the efficiency of the motor is greatly improved.

This insulative member 7 may be encapsulated within the housing 6, as shown in Fig 1, or embedded within the inner wall of the housing 6.

Additionally, Fig. 2 shows a cross sectional view of a blade 3. Generally, this blade 3 is made or constructed of a polymeric material. This polymeric material is shown as a layer which forms an insulative member 7a around the outer surface of the blade 3. Encapsulated within the blade 3 is a permanent magnet 11 surrounded by the insulative member 7a. As permanent magnets 11 may be generally comprised of bio-toxic compounds, it may be necessary to prevent the bio-toxic material from contacting the blood in the pump 13, when in use.

Most polymeric materials are at least partially susceptible to fluid permeation and as such bio-toxic compounds may degrade and release toxic chemicals or compounds in a patient's circulatory system. Therefore, it may be also preferable to coat the insulative member 7a in an impermeable barrier 12 to block, stop or greatly impede the eluting or release of bio-toxic compounds or chemicals into the patient's blood stream. The barrier 12 may also preferably encapsulate, coat and seal the permanent magnet 11.

Preferably, these barriers 12 may be constructed from gold, zinc, Paralene™ or similar impermeable coating material. Additionally the insulative member 7 may be surface modified so as to confer to the surface of the insulative member properties such as impermeability to fluids. These barriers 12 may be usable in any embodiment wherein the insulative member 7 is required to be sealed from the environment.

The insulative members 7 and 7a may be surface modified by plasma immersion ion implantation which may chemically alter the surface of the insulative members 7 and 7a to increase their hardness, durability and impermeability to fluids.

In Fig. 3, an enlarged top view of a preferred insulative member 7 is shown. This figure depicts a relatively flat disc shaped insulative member 7 mounted with three coils of wire forming the motor stators 5. This relatively flat insulative member may be adapted to fit in the lower inner surface of the housing 6 shown in Fig. 1. Alternately, the insulative member 7 may be modified to form a general cone shape suitable for use within the upper inner surface of the housing 6.

The following polymeric substances are examples of materials from which the embodiments may be constructed.

Polyetheretherketone ('PEEK')

An example of a polymeric material that may be used in the constructions of an embodiment is PEEK. It has a relatively high thermal stability compared with other thermoplastics. It typically retains high strength at elevated temperatures, and has excellent chemical resistance (being essentially inert to organics, and has a high degree of acid and alkali resistance). It has excellent hydrolytic stability and gamma radiation resistance. Therefore PEEK may be readily sterilised by different routes. It also shows good resistance to environmental stress cracking. It generally has excellent wear and abrasion resistance and a low coefficient of friction. PEEK may incorporate glass and/or carbon fibre reinforcements which may enhance the mechanical and/or thermal properties of the PEEK material.

PEEK may be easily processed on conventional extrusion and injection moulding equipment. Post-annealing and other processes obvious to a person skilled in the art may be preferable. A polyaromatic, semicrystalline polymer may also be used in construction of an embodiment.

Other examples of this polymer include: Polyaryletherketone ('PAEK') manufactured by Vicktrex and PEEK-OPTIMA LT™ which is a polymer grade with properties optimised for long-term implants. PEEK-OPTIMA LT™ is significantly stronger than traditional plastics currently available. Generally, PEEK may be able to withstand more aggressive environments and maintain impact properties over a broader range of temperatures than other polymers.

It has been shown that carbon fibre reinforced PEEK found to exhibit excellent resistance to a saline environment at 37°C designed to simulate human body conditions.

PEEK includes the significant advantage of generally supplying dimensional stability, when in use.

Fibre reinforced polymer ('FRP')

Another example of a polymeric material that may be included within an embodiment of the present invention is FRP. FRPs are constructed of composites of PEEK and other polymers. PEEK may be reinforced with 30% short carbon fibres and which when subjected to saline soaking, was found to exhibit no degradation in mechanical properties. In contrast, a 30% short carbon fibre reinforced polysulphone

composite has been found to show degraded mechanical properties due to the same saline soaking.

The fibre /matrix bond strength may significantly influence the mechanical behaviour of FRP composites. Interfacial bond strength durability is therefore particularly important in the development of FRP composites for implant applications, where diffused moisture may potentially weaken the material over time. Testing in physiologic saline at 37°C showed that interfacial bond strengths in carbon fibre/polysulfone and carbon fibre/polyetheretherketone composites significantly decrease.

It should be noted that the fibre/matrix bond strength is known to strongly influence fracture behaviour of FRP composites.

Polycarbonate ('PC')

Another example of polymer material that may be used in the construction of a preferred embodiment are PC resins. PC resins are widely used where transparency and general toughness are sought.

PC resins are intrinsically amorphous due to the large bulky bis-phenol component. This means that the polymer has a significantly high free volume and coupled with the polar nature of the carbonate group, the polymer can be affected by organic liquids and by water. PC resins are not as resistant to extremes in pH as PEEK however they are at least partially resistant.

PC resins generally have very low levels of residual monomers and so PC resins may be suitable for blood pump construction. PC resins generally have desirable mechanical and thermal properties, hydrophobicity and good oxidative stability. PC resins are desirably used where high impact strength is an advantage. PC resins also generally confer good dimensional stability, reasonable rigidity and significant toughness, at temperatures less than 140°C.

PC resins may be processed by all thermoplastic processing methods. The most frequently used process is injection moulding. Please note that it may be necessary to keep all materials scrupulously dry due to small but not negligible moisture pick-up of this resin. The melt viscosity of the resin is very high, and so processing equipment should be rugged. Processing temps of PC resins are relatively high generally being between approximately 230°C and 300°C.

Polysulphone ('PS')

Another example of a polymeric material that may be used to construct parts of an embodiment from is PS. PS has relatively good high temperature resistance, and rigidity. PC is generally tough but not notch-sensitive and is capable of use up to 140°C. It has excellent hydrolytic stability and is able to retain mechanical properties in hot and wet environments. PS is generally chemically inert.

PS is similar to PC resins but may be able to withstand more rigorous conditions of use. Additionally, PS is generally more heat resistant, and possesses a greater resistance to creep and better hydrolytic stability. PC has a high thermal stability generally due to bulky chemical side groups and rigid chemical main backbone chains. It is also generally resistant to most chemicals.

Injection moulding used for lower melt index grades, whilst extrusion and blow moulding is used to form components generally made of higher molecular weight PS.

Polyurethanes (PU)

Another example of a polymeric material that may be include within an embodiment of the present invention is PU. PU is one of the most biocompatible and haemocompatible polymeric materials. PU has the following properties: elastomeric characteristics; fatigue resistance; compliance and acceptance or tolerance in the body during healing; propensity for bulk and surface modification via hydrophilic/hydrophobic balance or by attachments of biologically active species such as anticoagulants or bio-recognisable groups. Bio-modification of PU may be possible through the use of a several antioxidants used in isolation or in combination. These antioxidants may include vitamin E, which may create materials which can endure in a patient's body for several years.

PU constitutes one of the few classes of polymers that include the properties of being generally highly elastomeric and biocompatible.

1. Polyether Polyurethanes ('PEPU')

Another polymeric material that may be used in the construction of an embodiment is PEPU. PEPU generally has: relatively good flexural performance and acceptable blood compatibility.

2. Polycarbonate Urethane ('PCU')

PCU may also provide another alternative polymeric material for the purpose of constructing an embodiment. PCU has significantly lower rates of water transmission or impermeability. This is due to inherently lower chain mobility of the carbonate structure in the soft segment phase. Additional impermeability to water vapour can be achieved by selecting a polyurethane polymer with high hard segment content, and aromatic rather than aliphatic di-isocyanate co-monomer, and a more hydrophobic surface.

PCU generally has oxidative stability of the carbonate linkage, which reduces the rate of biodegradation tremendously as compared to the polyether polyurethanes.

Siloxane-Urethanes ('SiU')

SiU is another example of an alternative preferred polymeric material. SiU generally has a combination of properties including: fatigue strength, toughness, flexibility and low interaction with plasma proteins. However these polymers may be relatively soft.

Polyvinylchloride ('PVC')

PVC is another example of an alternative preferred polymeric material. PVC is a relatively amorphous and rigid polymer which in the absence of plasticiser has a glass transition around Tg 75°C -105°C. It is a cheap tough polymer which is extensively used with many types of filler and other additives. Although it has a high melt viscosity and therefore in theory is difficult to process, specialised methods have been established for several decades to compound this polymer efficiently.

Extraction-resistant grades of PVC are required for long-term blood compatibility. Plasticised PVC has been well established for blood bags and similar devices, and resin manufacturers can keep toxic residual monomer levels acceptably low (<1ppm). However there is enormous social pressure to outlaw PVC despite scientific data which generally indicates that PVC is benign.

3. Poly vinylidene fluoride ('PVDF')

PVDF is a polymer that possesses relatively good amounts of toughness and biocompatibility to be suitable for use in constructing an embodiment.

Polyethylene ('PE')

PE is available in several major grades, including Low Density PE ('LDPE'), High Density PE ('HDPE') and Ultra High Molecular Weight Grade PE ('UHMWPE').

However the UHMWPE may be likely to be the most suitable as it generally possesses relative toughness, low moisture absorption, and good overall chemical resistance.

Sintered and compression moulded UHMWPE has been well established for hip joints replacement. However further improvements appear necessary, as abrasive resistance and wear are not suitable for lengthy (>5-10 year) use. A major limitation of PE is thermal performance (melting point approximately 130°C) and dimensional stability.

Polypropylene ('PP')

Another suitable polymeric material is PP. PP is a versatile polymer that may possess a combination of features including: relative inertness, relatively good strength and good thermal performance. Depending on the grade, Tg ranges from 0°C to -20°C and the MPt is approximately 170°C. The most common grades are homo- and ethylene copolymers, the latter with improved toughness.

In addition, there have been many advances in reactor technology leading to grades which are either much softer than normal or much stiffer. For example, the Bassell Adstiff™ polymers made using Catalloy™ technology may be suitable and/or include desirable features for use in the manufacture of a blood pump. Generally, PP polymers lack the high melting point of PEEK, but this property is not generally desired.

Polymethylmethacrylate (PMMA)

PMMA is an amorphous material with good resistance to dilute alkalis and other inorganic solutions, and has been shown to be one of the most biocompatible polymers. Therefore, PMMA may include some of the desirable features and may be used in the construction of an embodiment of the present invention. Generally, PMMA easily machined with conventional tools, moulded, surface coated and plasma etched.

PMMA's may be susceptible to environmental stress cracking although this is usually associated with the use of organic solvents, not present in a patient's body and a blood pump working environment.

Acrylonitrile-Butadiene-Styrene Terpolymers (ABS)

ABS generally have relatively good surface properties including: hardness, good dimensional stability and reasonable heat resistance (Tg approximately 120°C). The

combination of the three monomers imparts stiffness (styrene), toughness (butadiene) and chemical resistance (acrylonitrile).

Other attributes of ABS may include: rigidity, high tensile strength and excellent toughness as well as excellent dimensional accuracy in moulding. ABS is generally unaffected by water, inorganic solvents, alkalies; acids; and alcohols. However certain hydrocarbon solvents, not usually present within the body of a patient or in the working environment of the blood pump, may cause softening and swelling on prolonged contact.

Polyesters ('PET')

PET have become one of the largest growing thermoplastics over the past decade: volumes and prices are now approaching PE and PP. PET has a Tg around 75°C and melting point of 275°C. It can vary from about 25% to 70% in crystallinity depending on the processing history of the polymer. Physical properties and chemical resistance are very dependant on crystallinity. PET may also have limited dimensional stability, as crystallisation can slowly increase after moulding. PET are generally tough, transparent, stiff and opaque.

Another class of PET with a Tg above 100°C is currently available, this polymer is called Polyethylene Naphthenate ('PEN'). PET and PEN may both be suitable for use in the construction of a blood pump.

Polyamides and/or Nylons ('PA')

PAs and Nylons are characterised by having excellent wear/frictional properties, high tensile impact and flexural strength and stiffness, good toughness and high melting points.

Some PAs may include relatively large hydrocarbon spacers between the amide groups. Examples of this type of PA include Nylon 11 and 12 which are generally more hydrophobic (water uptake <1%) than regular varieties of PAs. However the larger spacing leads to a loss in stiffness compared to the other polymers and thermal performance may also be compromised.

Fully aromatic polyamides including Kevlar™ (*para* position) and Nomex™ (*meta* position) are commercially available and have high stiffness and melting points. Semi-aromatic polyamides are made in Germany (eg Trogamid™ T) and France. These semi-aromatic polyamides generally have good transparency and chemical resistance.

Acetal Resins and/or Polyoxymethylene ('AR')

AR may be used to construct any one of the preferred embodiments. This class of polymer is strong, hard, and abrasion resistant. It has been evaluated for joint replacement components and other long-term implants.

The acetal homo-polymer is prone to salt induced cracking, but copolymers with small amounts of a propylene oxide are possible. AR which contains formaldehyde may be of concern due to possible toxicity of formaldehyde.

Polydimethylsiloxane ('PDSM')

PDSM may be used to construct any one of the preferred embodiments. This polymer is generally elastomeric. It may also be considered for use as either a biocompatible coating or a copolymer.

Copolymers based on PDMS and PU have been developed and PDMS/PC is commercially offered by General Electric as Lexan™ 3200. The latter is a fairly stiff transparent material with excellent UV performance.

Syndiotactic Polystyrene ('SP')

SP may be used to construct any one of the preferred embodiments. SP is typically highly crystalline, little change in modulus occurs at the Tg of 100°C, and retention of properties is fairly high to the melting point of over 250°C. Many grades may be fibre reinforced, to further reduce the change in modulus at the Tg. Being a hydrocarbon with no hetero atoms, the polymer may be hydrophobic and inert.

Aliphatic ether ketones ('AEK')

AEK may be used to construct any one of the preferred embodiments. Processing and mechanical performance are similar, but this polymer shows improved high temperature aging behaviour and little notch sensitivity. Unfortunately the material lacked distinctiveness and is no longer produced.

TOPAS™ ('T')

T may be used to construct any one of the preferred embodiments. This class of co-polymer is made by Ticona in Germany. It generally comprises ethylene and norbornadene, with the Tg being controlled by monomer ratio. It is a hydrocarbon alternative to polycarbonate, and is generally suitable for medical fittings and devices.

Its Tg is over approximately 130°C and it is generally transparent with the co-monomer inhibiting crystallisation of the ethylene segments.

Metallocene PP ('MPP')

MPP may be used to construct any one of the preferred embodiments MPP is manufactured by Exxon to compete with existing PP. It has a much narrower molecular weight distribution (polydispersity around 2) because it is oligomer-free.

Various additional modifications are possible within the scope of the foregoing specification and accompanying drawings without departing from the scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A rotary blood pump including: a motor adapted to magnetically rotate an impeller within a housing; characterised in that the impeller or the housing are formed of a composite material and said composite material includes a first material that is a relatively, insulative, biocompatible and impermeable polymer and wherein the pump includes an insulative member formed from said first material and is disposed between portions of the motor to reduce eddy currents losses.

2. The rotary blood pump as claimed in claim 1, wherein the composite material includes a second material that reinforces the polymer.

3. A rotary blood pump as claimed in claim 1, wherein said first material has been surface modified by treatment of plasma immersion ion implantation.

4. A rotary blood pump as claimed in claim 1, said impeller includes magnets that are encapsulated by an impermeable fluid barrier.

5. A rotary blood pump as claimed in claim 1, wherein said first material is: PEEK, FRP, PC, PS, PEPU, PCU, SiU, PVC, PVDF, PE, PMMA, ABS, PET, PA, AR, PDSM, SP, AEK, T, MPP or a combination thereof.

6. The rotary blood pump as claimed in claim 1, wherein said impeller is hydrodynamically suspended.

7. A rotary blood pump including: a motor adapted to magnetically rotate a hydrodynamically suspended impeller within a housing; characterised in that the impeller and/or the housing are formed of a composite material, said pump including at least one insulative member disposed between portions of said motor to reduce eddy current losses and said insulative member is substantially formed from a biocompatible and impermeable polymer.

8. A rotary blood pump as claimed in claim 7 wherein said composite material includes a metal metallic alloy.

9. A rotary blood pump as claimed in claim 8 wherein said metallic alloy is a titanium alloy.